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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/849,525	08/29/1997	GHITA LANZENDORFER	435-WCG	3976

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EXAMINER	
SHARAREH, SHAHNAM J	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 01/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/849,525	LANZENDORFER ET AL.	
	Examiner	Art Unit	
	Shahnam Sharareh	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-34* is/are pending in the application.

4a) Of the above claim(s) *25-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 23, 2003 and October 19, 2004 has been entered.

2. Applicant's election with traverse of Group I, claims 19-24 and the species of alpha-glucosylrutin wherein hydroxycinnamic acid and/or cinnamic acid derivatives are optional in Paper filed on October 19, 2004 is acknowledged. The traversal is on the ground(s) that the PCT rules allows for examination of the claims directed to the use of an entire genus and the product claims directed to a single species. (see Arguments Subheading B). Examiner does not dispute such guidelines, however, Examiner draws applicant's attention that the use claims exemplified in PCT guidelines are directed to the entire genus encompassing the species in the product claims.

3. Here, the situation is different. Applicant claims methods of use for a closed set of species, and on the other hand, claiming products directed to different species that are not the same in the method claims. The method of use is not directed to the use of the entire genus of flavonoids. Neither are the product claims directed to those species recited in the method of use claims. There is only one single species that is recited in both sets of claims, but Applicant has not elected such species for Examination on

merits. Moreover, Applicant has not provided any evidence or show any recoreds now of record that all species of flavanoids are obvious variants of each other. Therefore, Examiner has construed each flavonoid reicted in the instant claims to be patentable over the other that would provide unique clinical properties.

Moreover, the term "special technical features" is defined as meaning those technical features that define ***a contribution*** which each of the inventions considered as a whole, makes over the prior art see MPEP 1893.03(d), requiring the claimed inventions to be linked in the manner that they form a general inventive concept. In the instant case, belonging to a common family of flavanoids does not form a general inventive concept, because it is the shared characteristic of all natural flavonoids not a common inventive step, a shared technical feature, an inventive link between all the claims, nor is it viewed as a contribution over the prior art.

4. With respect to Applicant's neither arguments about the Election of Species, Examiern states, neither species of Group I, nor the Markush species of claim Group III are so linked as to form a single general inventive concept. Each species can be practiced for different characteristics for the reasons of record. thus, they are viewed to lack a common special technical feature for the reasons set forth above. The election of species requirement is soley based on the lack of a single inventive concept among the groups set forth in claim 19, 25, 30-34, regardless of their generic chemical structure. There is no commonality among the compositions set forth in claim 30-34. For example, each set of claims are directed compositions comprising containing other conventional cosmetic ingredients such as antioxidants. Applicant has not provided any evidence,

now on record, or argued that such species are obvious variants of each other. Thus, the requirement for the election of species is also proper.

5. Finally, Applicant appears to raise the issue that the Examiner is not entitled to raise a non-unity objection once the issue has been described in the international phase or prosecution history. (see Arguments at page 14 under the subheading C). In response, the Applicant's attention is drawn to MPEP 1893.03 (d), U.S. National Application Filed Under 35 U.S.C. 371. § 1.499 *Unity of invention during the national stage*. Accordingly:

> If the examiner find that a national stage application lacks unity of invention under § 1.475, the examiner may in an Office action require the applicant in the response to that action to elect the invention to which the claims shall be restricted. Such requirement may be made before any action on the merits but may be made at any time before the final action at the discretion of the examiner. Review of any such requirement is provided under § § 1.143 and 1.144.

As described in the Requirement, each Group is viewed to be directed to three independent methods, thus, the restriction for examination purposes is proper. Currently the case is under Continued Examination and has not reached a final action, therefore, the restriction requirement is consistent with the PCT guidelines.
Claims 25-34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper filed on October 19, 2004.The requirement is still deemed proper.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 19-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suzuki et al US Patent 5,145,781 in view of Middleton et al (Middleton) (Middleton and Chithan, *The Flavonoids, Advances in Research Since 1986*, 1994, Chapman & Hill, London, Ch. 15, pp 619-645, already on record), Harrrison's (*Harrison's Principles of Internal Medicine*, 1994, New York, McGraw-Hill, Inc., 13th edition, pp. 309-313, already on record).

The instant claims are directed to methods of using cosmetic or dermatological formulations comprising flavonoids such as alpha glucosyl rutin, optionally one or more cinnamic acid derivatives and optionally an antioxidant. The instant immunosuppression encompass any type of biological effects that cause attenuation of immune system.

Applicant is informed that during patent examination, the pending claims are given the broadest reasonable interpretation consistent with the specification. Accordingly, the recitation of "optionally" does not limit the instant formulations to the recited optional component.

7. Suzuki et al disclose α-glycosyl rutin which is a flavonoid encompassed by the instant claims. Suzuki discloses various uses of α-glycosyl rutin (col 8, lines 45-56; col 10, lines 4-30). Suzuki discloses cosmetic compositions comprising α-glycosyl rutin (see col 19-20). Suzuki specifically discloses the use of such rutin as UV absorbant. (col 8, lines 45-55, col 22, lines 45-67). Suzuki teaches the use of his compositions for immune conditions such as malignant tumors. Suzuki also teaches the incorporation of antioxidants. (see col 21, lines 1-25). Suzuki meets all elements of the instant claims except its use for immunosuppression of skin cells induced by UVB radiation.

8. Middleton is merely used to show the plethora of information about the effects of flavonoids on immune system (pp 619-620). Accordingly, it is well within purview of an ordinary skill to modulate the activity of immune system by administering flavonoids of interest (Ch. 15, pp 619-645). For example, genistein have been shown to inhibit T-lymphocyte activity by inhibiting protein tyrosine kinase (see pp 625, 2nd col, 1st paragraph). Quercetin has been effective in regressing the spread of fibrosarcoma in vitro (see pp 627, 2nd col). Similarly, flavonal glycosides such as mauritanin and myricitrin have been shown to improve the delayed-type hypersensitivity among mice undergoing two-stage carcinogenesis (see top of pp 628).

Moreover, like alpha glucosyl rutin, topical quercetin has been effective in preventing and improving various immunosuppressive conditions associated with skin cancer (see pp 642, 3rd -8th paragraphs). Therefore, the general knowledge available in the art provides for the beneficial effects of topical flavonoids in improving immunosupresseive conditions regardless of their etiology.

9. Harisson's is used to show the general knowledge in the art about the etiology of solar radiation and systemic immune response caused by UV-B exposure (see pp 309 last paragraph). Accordingly, the immunesuppression caused by UV-B is caused by the induction of suppressor T cells throughout the body.

10. Middleton and Harisson's collectively teach the general knowledge of an ordinary skill in the art of medicine and immunology about the beneficial effects of flavonoids on immune system; and the etiology of immunosuprression cause by UV-B.

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to apply Suzuki's formulations topically to modulate immune suppressions caused by UV-B exposure, because as taught Harrison's, such immunosuprression is dependent on the activity of T-lymphocyte which as taught by Middleton, can be controlled by topical administration of a flavonoid of choice.

Thus, one of ordinary skill in the art understanding the etiology of UV-B induced skin conditions would have had a reasonable expecatiaotn of success in applying Suzuki's formulations for its immunologic effects because as taught by Middleton, the ordinary skill in the art would have had a reasonable expectation of success for its beneficial immune effects.

11. Moreover, the instant method claims 19 and 25 are not limited to any specific etiology associated with UV-B induced immunesuppression; rather, said claims are limited to the recitation of a single method steps, wherein the method comprise applying to the skin of a person an effective amount of one or more flavonoids, as recited in the body of the claim. Accordingly, the instant claims are *prima facia* obvious, because the

ordinary skill in the art would have known of various beneficial effects of flavonoids on immune system when using Suzuki's compositions topically, because

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 19-24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 4 of U.S. Patent No. 5,952,373 ('373), claims 1-5 of U.S. Patent 6,121,243 ('243), claims 1-2 of U.S. Patent 6,562,794 ('794). Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of both sets of claim overlaps in the manner that one renders the other obvious.

For example, claims 4 of '373 are directed to compositions comprising one or more flavonoid and other optional ingredients such as an antioxidant. Thus, it would have been obvious to one of ordinary skill in the art at the time of invention to make the similar compositions as instantly claimed by incorporating an alpha glucosyl rutin as the flavonoid of choice.

Similarly, claims 1-5 of '243 are directed to methods of preventing or treating skin wrinkles against inflammation of skin caused by exposure to oxidation, which encompass sun and UVB exposure. Thus, the scope of the patented claims overlap with the scope of the pending claims and one of ordinary skill in the art would have been motivated to use the patented claims for the same reasons as instantly claimed invention.

13. Claims 1-2 of '794 are directed to methods of applying alpha glucosyl rutin. Thus, the scope of the patented claims overlap with the scope of the pending claims and one of ordinary skill in the art would have practiced the scope of the pending claims when in possession of the patented claims.

Conclusion

14. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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